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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,700	01/09/2003	Robert Paul Anderson	HO-P02416USO	2705
34141	7590	08/26/2005	EXAMINER	
COZEN O' CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER

1644

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,700

Applicant(s)

ANDERSON ET AL.

Examiner

David A. Saunders, PhD

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 112-165 is/are pending in the application.
- 4a) Of the above claim(s) 120-122, 124-127, 132-135, 139-142, 152-163 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 112-119, 123, 128-131, 136-138 and 143-151 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Amendment of 6/14/05 has been entered. Claims 112-163 are pending. Claims 112-119, 123, 128-131, 136-138 and 143-151 are under examination. No new matter has been entered.

The following corrections pertain to the previous Office action:

At page(s) 3, last line "118" should have read as --18--.

The disclosure is objected to because of the following informalities:

In the SEQ ID listing, references to "homo sapiens" appear to be unintended, at the least for SEQ ID NO:3, which is a natural gliadin from plants.

Appropriate correction is required.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment has overcome previously stated issues as follows:

The rejection of claims 115, 128, 144 under 35 USC 112, 2nd paragraph.

The rejection of claims 143-144 and 151 under 35 USC 112, 1st paragraph pertaining to new matter.

The following rejections of record are maintained or modified as follows:

Claims 123, 128-131, 138, 146, 149 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 123 is confusing in its definition of the “analogue”. It is not clear whether the modification that renders this peptide an “analogue” is within SEQ ID NO:1, or in a sequence adjacent thereto.

Claim 128 is confusing in its definition of the “analogue” at lines 16-19. It is not clear whether the modification that renders this peptide an “analogue” is within SEQ ID NO:1, or in a sequence adjacent thereto.

In claim 129 the preamble is unclear by claiming a “composition” as a Markush group of members which include “a composition”. Line 17 must conclude with an —and—in order to set off the “wherein” of line 18.

Claim 129 is confusing in its definition of the “analogue” at lines 18-21. It is not clear whether the modification that renders this peptide an “analogue” is within SEQ ID NO:1, or in a sequence adjacent thereto.

In claim 138 “the antibody-IFN.gamma.complex” and in claim 149 “the antibody-cytokine complex” lack antecedent basis. Applicant has urged with respect to claim 138 that the antibody and the IFN.gamma. would inherently form a complex. This fact may be recognized by those of skill; however, the claim could be litigated and interpreted by those not of skill. Applicant could correct by substituting —optionally comprises means to detect any complexes formed between the antibody and IFN.gamma.—

In claim 146 “before determining in vitro” is unclear because “in vitro” has been deleted from claim 143.

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Claims 116-119, 128-131, 136-138, 143-151 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite new matter, for reasons of record.

Firstly claims 116-118 contain new matter by reciting "and other/gliadin/non-gliadin sequence" without limiting the other sequence to one that is fused, as in dependent claim 119. The examiner only finds fusion proteins and not other kinds of polypeptides (e.g. conjugates of SEQ ID NO: 1 and another peptide) described at page 10, Line 15, page 22, line 10). Dependent claims 136-138 and 143-151 are included in this rejection.

Applicant has urged that page 10, lines 15-17 support; however, the examiner finds that the text therein specifically mentions a "fusion protein" and nothing else. Page 11, lines 24-31 offers nothing to support, since this para. is referring to a composition of multiple agents, rather than to a fusion protein or a conjugate of the multiple agents.

Secondly, the examiner finds no description for the fusion of SEQ ID NO: 1 to another gliadin sequence, as in claims 116-117 and in claim 128, lines 2-15 and claim 129, Lines 3-17. The examiner only finds support for fusion of SEQ ID NO: 1 to a non-gliadin sequence (page 10, Lines 15-17). In the case where there is fusion to another gliadin sequence (or more than one thereof), it appears that the fusion is of a mutated form of the disclosed sequences (e.g. SEQ ID NO: 1 of 2) to the gliadin sequence. See page 22, lines 3-12. Applicant is thus claiming more embodiments than originally disclosed. Dependent claims 136-138 and 143-151 are included in this rejection.

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Applicant has urged that page 11, lines 24-31 support; however, as noted supra. the examiner finds that this para. is referring to a composition of multiple agents, rather than to a fusion protein or a conjugate of the multiple agents. Page 23, line 27 to page 14, line 5 offers nothing to support, since this para. is referring to a polynucleotide encoding "the sequence of SEQ ID NO: 1 or 2 or any of the agents mentioned herein" in the alternative and states nothing about a polynucleotide encoding multiple epitopic sequences from different gliadin proteins. Applicant's argument is that these various passages should be "taken together" to provide support. When one interprets the passages "taken together" there might be some stretched basis for obviousness of, but not an explicit basis for describing, what is now claimed; applicant is reminded that what might be obvious fails to provide a basis for description. *Lockwood V. American Airlines* 41 USPQ2d 1961.

Claims 116-117, 128-131, 136-138, 143-151 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has not disclosed how to use the invention in which SEQ ID NO: 1 or 2 is fused to another gliadin Sequence. As noted supra, under the 112 new matter rejection, it appears that applicant only disclosed the making and using of a mutated form of SEQ ID NOS: 1 or 2 to another gliadin sequence. One thus does not know whether the instantly claimed fusion polypeptides are to be used in diagnostic testing, in immunizing, or in tolerizing treatments. Dependent claims 136-138 and 143-151 are included in this rejection.

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Applicant has urged that the invention is enabled; the examiner does not deny that one of skill might be able to figure out a way to use the claimed peptides in diagnostic testing, in immunizing, or in tolerizing treatments. The problem is that applicant did not describe these peptides and, in so failing, did not particularly tell the reader how one is to use these peptides.

Applicant's arguments filed 6/14/05 have been fully considered but they are not persuasive for the reasons above.

Upon reconsideration the following grounds of rejection are newly stated.

Claims 112-117, 119, and 128 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicant is claiming a product of nature.

At spec. page 33 applicant admits that gliadin peptides were treated with tTG to generate products that might mimic those produced in vivo. It appears from the following disclosure (pp 34-35) that gliadin peptides with the Gln at position 65 modified to Glu occur naturally in humans with coeliac disease, since the disclosure shows that subjects with coeliac disease show T-cell reactivity to tTG treated peptides including modified residue 65. While the exact length of the peptides that may be produced in vivo may not be known, it is clear that any naturally occurring, longer peptide including the 7-mer of SEQ ID NO:1 or the 16-mer of SEQ ID NO:2 would be encompassed by the claim. The fusion protein of Claim 119 is included with the rationale that SEQ ID NO:1 fused to an adjacent gliadin sequence (as is consistent with claim 116) would be a naturally occurring product in patients with coeliac disease. The peptide mixture of claim 128 is included because one of skill would reasonably expect the digestive system of an individual to yield peptides of varying lengths that include the modification at residue 65.


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Applicant may overcome by reciting --isolated-- before "peptide" in each of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu., 8:00 am-5:30 pm and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8/17/05 DAS


DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644